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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 211.313

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on August 28, 2009

Signature Connie Bursey

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Typed or printed name Express Mail No. EM 098652278 US

Application Number	Filed
10/665,742	September 17, 2003

First Named Inventor: Magnus Bolmsjo

Art Unit	Examiner
3761	Adam M. Marcetich

Applicant requests review of the ~~final~~ last rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 27,453
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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August 28, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Pre-Appeal Brief Request for Review

Pre-appeal review is respectfully requested of clear legal and factual errors in the obviousness rejections of claims 1 and 34 in the March 30 Office Action ("3/30 Action"). A pre-appeal review request involving similar issues and much of the same prior art has been filed in CIP application 11/246,801.

Claims 1 and 34 define an indwelling catheter that allows a man to urinate naturally when benign prostatic hyperplasia (BPH), disease or prostate surgery, has constricted his prostatic urethra and inhibited urine flow. See appl., p. 1, l. 14-p. 5, l. 7.

A catheter 20 (Fig. 8) has a main body 58 which is positioned in an indwelling, normal-use position within the prostatic urethra 28. An upstream or "distal" end 38 is located in the bladder 32, and a downstream or "proximal" end is located immediately distal or upstream of the external urinary sphincter muscle 34. A balloon 40 on the distal end 38 is inflated in the bladder by fluid from an inflation tube 44. The inflated balloon 40 anchors the catheter 20 against downstream migration by contact with the bladder neck 46. A coiled section 54 of the inflation tube 44, located downstream or proximal of and adjacent to the sphincter 34, contacts the constricted sphincter 34 to anchor the catheter 20 against upstream migration. The main body 58 conducts urine from the bladder through an interior passageway 56 to the sphincter muscle 34. Voluntary dilation and constriction of the sphincter 34 around the inflation tube controls urine flow from the passageway 56 into the urinary canal 26. Normal urinary function is preserved by the voluntary control over the sphincter muscle 34, despite swelling of the prostate gland 30 and constriction of the prostatic urethra 28.

I. Ressemann does not describe restraint from a coiled inflation tube.

Patentability of claims 1 and 34 centers around the coiled section of the inflation tube acting as the downstream restraint against upstream migration. See 3/30 Action, p. 3, l. 16-p. 4, l. 9; ¶13. The Examiner erroneously asserts that Ressemann describes a coiled section of an inflation tube acting as a restraint within a vessel. See 3/13 Action, p. 3, l. 16-17; p. 4, l. 1-9; p. 18, l. 17-18; and ¶¶15, 27 and 28.

Ressemann describes an angioplasty catheter 10 inserted into a blood vessel to expand a restricted part of the vessel. A longitudinal compressible section 22 allows the catheter to be shortened for insertion over and removal from a guide wire 17 that has been previously located in the vessel (Abstract). A coiled tube 31 extends through

the collapsible section 22 to accommodate the longitudinal compression and to supply fluid to a balloon 12 (col. 5, l. 58-62). The balloon 12 is inflated to enlarge the restricted part of the vessel, after the catheter 10 is positioned appropriately. A sheath 32 covers the coiled tube 31 (col. 5, l. 5-33). A rigid actuating member 16 extends through the collapsible section 22 and is connected between an exterior manifold 13 and the front end of the catheter to establish the desired length of the catheter and to locate the balloon 12 adjacent to the restricted vessel part (col. 5, l. 22-29). When the actuating member 16 is rigid and straight, it may serve as the inflation tube (col. 4, l. 61-65).

Ressemann does not anchor the angioplasty catheter within the vessel. The catheter slides into and out of the vessel without significant friction, resistance, anchoring force or other risks of damaging the vessel. If it did not, the use of the catheter would create additional medical problems. The catheter is restrained outside of the vessel and the patient by locking the adjusted length of the rigid actuating member 16 to the external manifold 13 (col. 4, l. 23-28, l. 61-65; col. 5, l. 22-29, 46-52; col. 2, l. 37-43). The sheath 32 prevents the coiled tube 31 from contacting the vessel wall or restraining movement of the catheter. The tube 31 is coiled for collapsible flexibility, not for restraint. There is nothing comparable to the sphincter muscle in the vessel by which to restrain the Ressemann catheter.

Claims 1 and 34 have been erroneously rejected because of the mistaken belief that Ressemann's flexible inflation coil performs an anchoring function in the vessel.

II. The combined references do not reach the scope of the claims.

Rioux, another reference applied in rejecting claims 1 and 34, describes an indwelling catheter having a downstream "bulbar" tube segment 20 connected by a thread-like tie 5 to an upstream "prostatic" tube segment 19 (col. 4, l. 38-col. 5, l. 26). The tie 5 spaces the segments 19 and 20 on opposite sides of the external sphincter muscle 10 so it can control urine flow (Fig. 2b, col. 6, l. 30+). A flexible inflation tube 3 (Fig. 3, col. 7, l. 40-45) extends through the downstream tube segment 20. The tube segment 20 interacts with the sphincter 10 to restrain against upstream migration. The tube segment 20 surrounds the inflation tube 30 downstream of the sphincter and prevents the inflation tube 30 from interacting with the sphincter 10.

Rioux's inflation tube 30 is isolated from restraining interaction with the sphincter by the surrounding downstream tube segment 20. Ressemann's coiled inflation tube

31 is surrounded by the sheath 32 (Fig. 5), thereby isolating the tube 31 from restraint with the sphincter.

Neither Rioux nor Ressemann states that the inflation tube can be used as a restraint. The structural features of Rioux and Ressemann prevent the inflation tube from acting as a restraint against the sphincter. Therefore, the combination of Rioux and Resseman fails to meet the claim limitation of the coiled section interacting with the sphincter to restrain against distal movement. (Claim 1, l. 23-27; claim 34, l. 22-26)

III. Rioux and Ressemann were combined by hindsight.

As noted, Rioux does not teach using the inflation tube as a restraint, because the downstream tube segment 20 is explicitly used for restraint and that tube segment 20 isolates the inflation tube from interaction with the sphincter. Ressemann does not teach restraining the angioplasty catheter from within the blood vessel, because restraint arises outside the blood vessel and in-vessel restraint may damage the vessel. Rioux and Ressemann each surround the inflation tube by another structure which prevents restraint against the sphincter, urinary canal or vessel.

As an angioplasty catheter, Ressemann is irrelevant to an extended-use indwelling urinary catheter located in the urinary canal. References relevant to indwelling urinary catheters restrained relative to the sphincter to permit it to control urination are Rioux, Devonec, Whalen 2003/0208183 and Eshel 5,916,195 (European counterpart 0 935 977). These relevant references do not suggest using an inflation tube for downstream restraint against upstream migration. These relevant references use an inflation tube only for inflation and use a separate downstream restraint only for restraint. Only this invention achieves inflation and restraint from the inflation tube.

The Examiner departs from relevant prior art to cite art from the field of blood vessel angioplasty, even though it is dissimilar and irrelevant in almost every significant regard, and even though it fails to disclose an inflation tube restraining against a sphincter muscle. Ressemann's only relationship to the invention is the structural feature of a coiled inflation tube. However, that coiled inflation tube is used for an entirely different purpose, in an entirely different catheter, which is applied in an entirely different manner, to execute an entirely different procedure, to remedy an entirely different medical condition in an entirely different way. Recognizing these differences reveals that the structural aspect of the coiled inflation tube is the true reason why

Ressemann has been combined with relevant references, not because a person skilled in the urinary catheter art would look to angioplasty art for guidance.

That Ressemann has been combined with hindsight is further shown by the failure to articulate a meaningful rationale for the combination, in contravention of MPEP 2141 (III) and 2143. The "consolidating parts" rationale (3/30 Action, p. 4, l. 20) is taught only by the present application, not by the prior art. While the expectation of an advantage is a recognized motivation for a combination, such an expectation or the advantages of the present invention did not exist until the Applicant taught them.

Hindsight is further demonstrated by the Examiner's unsupported assumption that the coiled inflation tubing in Ressemann is "capable of" restraint with a nonexistent sphincter muscle. See 3/30 Action, p. 4, l. 9; p. 11, l. 21. The Examiner's assumption is contrary to Ressemann's explicit description of restraint outside of the vessel. Only the present invention explains restraint from the coiled section of the inflation tube within the urinary canal.

Hindsight is also evident in the Examiner's acknowledged necessity to speculate about where the coiled section of the Rioux-Ressemann catheter would be located (3/30 Action, p. 4, l. 4-6). The Examiner speculates that the coiled part would be located "downstream relative to a catheter distal end" (3/30 Action,¶ 20), or "at one end" of the catheter (3/30 Action,¶ 25), or at a "proximal location" (3/30 Action,¶¶16, 20). Only the present application teaches that the coiled section must be located adjacent to, proximal of and in restraint against the sphincter. Speculating about the location of the coiled section shows that the theoretical Rioux-Ressemann modified catheter fails to teach the invention, and the gap has been filled by erroneous hindsight.

IV. The evidence as a whole has not been considered.

The differences between the prior art and the claimed invention must be considered as a whole. MPEP 2141.02. Such consideration must extend to all inherent properties, secondary considerations and other benefits and advantages resulting from the invention. MPEP 2141.02 and 2145.

Declarations from the two highly-accomplished medical and technical inventors, Magnus Bolmsjö, Ph.D., and Sonny Schelin, M.D. and Ph.D., were filed February 23 and 20, 2009, respectively. These declarations contain substantial evidence of many technical, medical and commercial improvements, benefits and desirable aspects of the

claimed invention, as well as patentability.

The record reveals that the Examiner did not consider either of these highly relevant Declarations. The Examiner apparently considered an unknown declaration of January 21, 2009 (3/30 Action, ¶ 23), but the Applicant filed no declaration on that date in either this application or in the related CIP application 11/246,801.

Assuming that the Examiner considered one or more of the declarations filed in this application or in the related CIP application, and that the date stated in ¶ 23 is an error, the Examiner's consideration appears to have been limited inappropriately to structural aspects of the invention, because only structural aspects are addressed by the Examiner. See 3/30 Action, ¶¶24-31. Examiner has failed to consider the important evidence of substantial benefits to medical practitioners and patients arising from the present invention, discussed in Dr. Bolmsjö's Declaration (¶¶ 10-30, 31l., and 32) and in Dr. Schelin's Declaration (¶¶ 10-25 and 38). Both Declarations present significant evidence of non-obviousness and of improvements in urinary catheters, which the pre-appeal review panel should consider in its entirety.

As examples of the nonobvious improvements from this invention discussed in the Declarations, using the coiled inflation tube section as a restraint avoids or suppresses infection and irritation (Bolmsjö ¶¶ 17, 19; Schelin ¶¶ 23, 25), and permits normal use and functionality even if the catheter is inadvertently displaced slightly upstream (Bolmsjö ¶ 27; Schelin ¶¶ 19). Neither of these two significant improvements is possible from the Rioux-Ressemann combination, because Ressemann's sheath 32 surrounding the coil prevents attaining these improvements. As another example, using the coiled section of the inflation tube facilitates removal from the urinary canal after use of the catheter is completed, because the coiled section is not a restriction or complication during removal (Bolmsjö ¶¶ 24, 25; Schelin ¶ 38). These and other improvements discussed in the Declarations are significant. Had the present invention been obvious, the urinary catheter art would have revealed these significant advantages and the Examiner would not have had to cite angioplasty art or to have used hindsight.

In conclusion, the obviousness rejections of claims 1 and 34 in the 3/30 Action is erroneous and should be withdrawn. Allowance of the pending claims is requested.

Respectfully submitted,

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